

February 27, 2013

Deborah Harvey
Division of Public Health
417 Federal Street
Dover, DE 19901

RE: DPH Proposed Newborn Screening Regulation [16 DE Reg. 827 (February 1, 2013)]

Dear Ms. Harvey:

The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed the Division of Public Health (DPH) proposal to adopt extensive revisions to its regulation covering screening of newborn infants for metabolic, hematologic, endocrinologic and certain structural disorders. The GACEC would like to share the following observations.

First, in §1.0, the original regulation contained a second "sentence" beginning "(T)hese regulations describe...". The superseding revision is grammatically incorrect. It is not a sentence: "To regulate the procedures for the Newborn Screening Program where each newborn delivered in the state must be provided a panel of screening tests to identify certain metabolic, hematologic, endocrinologic and certain structural disorders that may result in developmental delay, cognitive disabilities, serious medical conditions, or death."

Second, in the same "sentence", Council recommends deletion of the word "certain" between "identify" and "metabolic". Compare comparable provisions in title to §4.0, §4.1, and 6.1. The definitions of "endocrinologic disorder", "hematologic disorder", and "metabolic disorder" are not restrictive. Indeed, the definition of "metabolic disorder" refers to "include, but are not limited to...".

Third, the regulation sometimes refers to an "institution" and sometimes refers to a "facility". The term "institution" is used in §§1.0, 5.2, 7.2, 9.1, 9.2, and 10.1. The term "facility" is used in §§1.0, 4.1.1, 4.3, 6.1.1, 6.1.3, 6.2, and 6.3.1. The Delaware Manual for Drafting Regulations issued by the Register of Regulations offers the following guidance:

6.2.2. Strive for consistency in terminology, expression and arrangement. Avoid using the same word or term in more than one sense. Conversely, avoid using different words to denote the same idea. ...

The GACEC recommends using the term “facility”.

Fourth, in §2.0, definition of “hematologic disorder”, the term “result” should be “results”.

Fifth, the structure of §4.0 merits overhaul. Both §§4.1 and 4.3 purport to establish a sequence of responsibility for assuring collection and submission of results. Both sections contemplate parental responsibility. Council queries whether a parent of a child born in a hospital should be made responsible for collection and submission of results if “overlooked” by the hospital. Section 4.1 covers hospitals and non-hospitals. Section 4.3 overlaps, covering non-hospitals. An undefined “primary care provider” is made responsible before a parent or guardian. Thus, a grandparent providing most general care for an infant would be responsible for ensuring the screening before a parent or legal guardian. The Council suspects the Division intended to refer to “primary health care provider”. Compare §8.3.

Sixth, §6.1.1 refers to “no later than 3 days after birth...” The strikeout of “3” results in a confusing reference.

Seventh, in §7.1, some words are ostensibly missing from the following sentence: “The sample must be taken from every newborn who one or more of the following categories:...”

Eighth, in §7.1 and §7.2 – ‘hospital/institution of birth/hospital’ – one of the ‘hospitals’ is redundant.

Ninth, in §7.1.2, there is a typographical error on the second line, “designated unsatisfactory” by the laboratory. The quotation marks should be around “unsatisfactory”. The hyphen before ‘by’ may be the continuation of a strikethrough section and should be clarified.

Tenth, §11.0 refers only to “Hereditary Disorders”. This may not be co-extensive with “metabolic, hematologic, endocrinologic, and certain structural disorders”. It is unclear if abnormalities in any of these contexts could be non-hereditary (e.g. induced by oxygen deprivation during birth). If so, the reference to “Hereditary Disorders” may be too narrow.

Thank you for your time and consideration of our comments and recommendations. Please feel free to contact me or Wendy Strauss should you have any questions.

Sincerely,

Terri A. Hancharick
Chairperson

TAH:kpc